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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application of: Broome *et al.*

Application No.: 09/723,003

Group Art Unit: 3731

Filed: November 27, 2000

Examiner: Kevin Thao Truong

For: DISTAL PROTECTION DEVICE
AND METHOD

Attorney Docket No.: 10177-108

REQUEST UNDER 37 C.F.R. §§ 1.607 and 1.608(a)
FOR INTERFERENCE WITH A PATENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §§ 1.607 and 1.608(a), Applicants hereby seek to have an interference declared between the captioned application and Bates *et al.* Patent No. 6,179,859 B1 (the "'859 patent;" attached as Exhibit B), entitled "Emboli Filtration System and Methods of Use," which issued January 30, 2001 from application Serial No. 09/354,897, filed July 16, 1999. The '859 patent does not claim priority to any earlier-filed application.

The captioned application claims priority under 35 U.S.C. § 120 as a continuation of application Serial No. 09/035,740, filed March 5, 1998 (the "'740 application"), which issued as Patent No. 6,152,946 B1 on November 28, 2000.

This request is accompanied by a Declaration of Thomas E. Friebe Under 37 C.F.R. § 1.608(a), which is appropriate here since the captioned application is entitled to an effective filing date (March 5, 1998) prior to the effective filing date (July 16, 1999) of the '859 patent. Upon declaration of an interference, Applicants should be named senior party. This request is also accompanied by an Associate Power of Attorney to the undersigned, and others.

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In this Request, Applicants submit for the Examiner's consideration new claims 51-65 along with the following remarks. All prior pending claims have been canceled in this Request.

Applicants propose a single count directed to the same patentable invention claimed in the captioned application and the '859 patent. Claims 51-58 of the captioned application and claims 1-26 of the '859 patent should be designated to correspond to the proposed count. Applicants should be accorded benefit of the March 5, 1998 filing date of their application Serial No. 09/035,740 and Bates *et al.* should be accorded their July 16, 1999 filing date.

IN THE CLAIMS:

Please cancel claims 2-50, without prejudice.

Please add claims 51-58:

51. (new) Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:

- a guide wire having a distal region and a stop on the distal region;
- a capture ring disposed for translation on the guide wire, the stop limiting translation of the capture ring in a distal direction; and
- a filter sac connected to the capture ring.

52. (New) The apparatus of claim 51 wherein, when the filter sac is deployed in the vessel, rotation or distal translation of the guide wire relative to the capture ring does not displace the filter sac, but retraction of the guide wire in a proximal direction causes the stop to abut against the capture ring.

53. (New) Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:

- a guide wire having a first portion having a first diameter and a distal region having a second diameter greater than the first diameter; and
- a filter element having a capture ring disposed for translation on the first portion, the capture ring having an aperture greater than the first diameter but smaller than the second diameter,

wherein rotation or distal translation of the guide wire relative to the capture ring does not displace the filter element.

54. (New) The apparatus of claim 53 wherein the filter element comprises an expandable sac.

55. (New) The apparatus of claim 53 wherein the guide wire further comprises a flange disposed on the distal region having a diameter larger than the diameter of the aperture in the capture ring.

56. (New) A method of filtering emboli from blood flowing through a vessel, the method comprising:

providing a guide wire having a distal region including a stop, and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;

transluminally inserting the guide wire and filter element into a vessel;

deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;

advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.

57. (New) The method of claim 56 further comprising:

providing a delivery sheath; and compressing the filter element to a contracted state to insert the filter element within the delivery sheath.

58. (New) The method of claim 57 wherein the filter element comprises an expandable sac, and deploying the filter element comprises expanding the expandable sac so that a perimeter of the expandable sac contacts the wall of the vessel.

REMARKS

Upon entry of this Request, claims 51-58 will be pending. Claims 2-50 have been canceled by this Request; claim 1 was previously canceled. Claims 51-58 have been added by this Request.

I. BACKGROUND

The interfering subject matter relates to an apparatus for filtering emboli from blood, comprising a guide wire having a stop on the distal region; a capture ring

disposed for translation on the guide wire, the stop limiting translation of the capture ring in a distal direction; and a filter sac connected to the capture ring.

II. PROPOSED COUNT AND DESIGNATED CLAIMS

A. The Proposed Count

Applicants propose the following count:

PROPOSED COUNT

Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:

- a guide wire having a distal region and a stop on the distal region;
- a capture ring disposed for translation on the guide wire, the stop limiting translation of the capture ring in a distal direction; and
- a filter sac connected to the capture ring.

The proposed count is identical to claim 1 of the '859 patent. This is consistent with 37 C.F.R. § 1.606, which provides that "[a]t the time an interference is initially declared (§ 1.611), a count shall not be narrower in scope than any . . . patent claim designated to correspond to the count."

B. Claims 1-26 Of The '859 Patent Should Be Designated To Correspond To The Proposed Count

All claims of the '859 patent (claims 1-26) should be designated to correspond to the proposed count since all are directed to the same patentable invention. 37 C.F.R. § 1.601(n).

1. Claims 1-5 Are The Same Invention As The Proposed Count

Independent claim 1 is identical to the proposed count and therefore should be designated to correspond to the proposed count. None of claims 2-5, which depend from claim 1, adds any limitation that defines an invention separately patentable from claim 1 or from the proposed count, as discussed below.

Claim 2 adds the limitation to claim 1 that, when the filter sac is deployed in the vessel, rotation or distal translation of the guidewire relative to the capture ring does not displace the filter sac. Deployment of the filter sac results in the filter being abutted to the wall of the vessel lumen in a stationary position. As required by claim 1, the filter sac is connected to the capture ring and the capture ring is disposed for translation on the

guidewire. Therefore, any rotation or distal translation of the guidewire after the filter sac is deployed would not displace the filter sac since there is freedom of movement between the guidewire and the capture ring to which the filter sac is attached. There is nothing nonobvious about the result, which flows directly from the structure recited in claim 1, that rotation or distal translation of the guidewire would not displace the filter sac. Claim 2 also adds the limitation that retraction of the guidewire in a proximal direction causes the stop to abut against the capture ring. This limitation also defines a necessary result from the structural recitations in claim 1, namely, that there is a distal stop limiting translation of the capture ring in a distal direction. Since the stop prevents movement of the capture ring in a distal direction, retraction of the guidewire in a proximal direction necessarily results in the stop abutting the capture ring.

Claim 3 adds the limitation to claim 1 that the apparatus further comprises a plurality of self-expanding struts coupled between the filter sac and the capture ring. A filter element having a filter supported on a plurality of self-expanding struts is old in the art. See, for example, Patent No. 5,910,154 to Tsugita *et al.* (attached as Exhibit D), Figures 6A and 6B, described at column 12, lines 11-15 and 33-37. It would have been obvious to use self-expanding struts in the apparatus of claim 1 to connect the filter sac to the capture ring.

Claim 4 adds the limitation to claim 1 that the apparatus further comprises an elastomeric cone affixed to a distal portion of the filter sac. The use of elastomeric materials on the distal ends of devices for use in the vasculature is old in the art. See, for example, Patent No. 5,466,234 to Loeb *et al.* (attached as Exhibit E), Figure 1, described at column 3, lines 66-67. Thus, it would have been obvious to use an elastomeric cone on the distal portion of the filter sac of the apparatus of claim 1.

Claim 5 adds the limitation to claim 3 that the apparatus further comprises a cylindrical sleeve coupled between the plurality of self-expanding struts and the filter sac. This is also conventional in the art and in any event does not define a separately patentable invention over claim 1.

Therefore, claims 1-5 should also be designated to correspond to the proposed count since they are directed to the same patentable invention.

2. Claims 6-15 Are The Same Invention As The Proposed Count

Independent claim 6 is directed to the same patentable invention as the proposed count. None of claims 7-15, which directly or indirectly depend from claim 6,

adds any limitation that defines an invention separately patentable from claim 6, as discussed below.

Claim 6 differs from the proposed count by identifying that the stop of the guide wire is formed by a greater thickness in the guidewire at the distal end. There is nothing nonobvious about forming the distal stop recited in claim 1 by having an increased thickness at the distal end of the guidewire. Making the guidewire thicker at the distal end is one of many obvious methods for creating a distal stop on the guidewire. Claim 6 further differs from the proposed count by specifying that the capture ring of the filter element has an aperture greater than the narrower diameter of the guidewire (to facilitate translation over the guidewire), and less than the thicker diameter of the distal end of the guidewire (the stop). There is nothing nonobvious about the stop limiting translation of the capture ring by the greater thickness of the guidewire at its distal end. A thicker distal end of the guide wire is one of many means to create a stop. Claim 6 further differs from the proposed count by stating that rotation or distal translation of the guidewire relative to the capture ring does not displace the filter element. As with claim 2, if the filter is connected to the capture ring and both are free to translate along the guidewire (as specified in the proposed count), there is nothing nonobvious about the necessary result that movement of the guidewire does not displace the expanded filter element, since there is freedom of movement between the guidewire and the capture ring of the filter element.

Claim 7 adds the limitation to claim 6 that the filter element comprises an expandable sac. Such expandable filter sacs are old in the art in this kind of apparatus and the combination does not define a separately patentable invention.

Claim 8 adds the limitation to claim 7 that the filter element further comprises a plurality of struts coupling the expandable sac to the capture ring. A filter element having a filter supported on a plurality of struts is old in the art. See, for example, Patent No. 5,910,154 to Tsugita *et al.* (attached as Exhibit D), Figures 6A and 6B, described at column 12, lines 11-15. It would have been obvious to use struts in the apparatus of claim 1 to connect the filter sac to the capture ring.

Claim 9 adds the limitation to claim 8 that the struts are self-expanding. Self-expanding struts of a filter element are conventional in the art. See, for example, Patent No. 5,910,154 to Tsugita *et al.* (attached as Exhibit D), Figures 6A and 6B, described at column 12, lines 11-15 and 33-37. Use of self-expanding struts in the filter element does not define a separately patentable invention.

Claim 10 adds the limitation to claim 7 that the filter element further comprises an elastomeric cone affixed to a distal portion of the expandable sac. The use of elastomeric materials on the distal ends of devices for use in the vasculature are old in the art. See, for example, Patent No. 5,466,234 to Loeb *et al.* (attached as Exhibit E), Figure 1, described at column 3, lines 66-67. Thus, it would have been obvious to use an elastomeric cone on the distal portion of the filter sac of the apparatus of claim 6.

Claim 11 adds the limitation to claim 6 that the guidewire further comprises a flange disposed on the distal region having a diameter larger than the diameter of the aperture in the capture ring. There is nothing nonobvious about forming the distal stop recited in claim 6 by using a flange having an larger diameter than the aperture of the capture ring itself. Use of such a flange at the distal end is one of many obvious methods for creating a distal stop on the guidewire and does not constitute a separately patentable invention over claim 6.

Claim 12 adds the limitation to claim 8 that the filter element further comprises a cylindrical sleeve coupled between the plurality of struts and the expandable base. This is also conventional in the art and does not define a separately patentable invention over claim 6.

Claim 13 adds the limitation to claim 7 that the filter element further comprises a distal ring coupled to the expandable sac, the distal ring having a bore with a diameter greater than the second diameter. This additional limitation does not define a separately patentable invention over claim 7.

Claim 14 adds the limitation to claim 6 that the filter region has a contracted state suitable for transluminal delivery, and that the distal region has a length that is greater than that of the filter element in the contracted state. These are merely design choices that do not define a separate patentable invention from claim 6.

Claim 15 adds the limitation that the filter region has a contracted state suitable for transluminal delivery and that the apparatus further comprises a flexible catheter having a lumen and a push tube disposed in the lumen, the push tube having a guide wire lumen for accepting the guide wire, wherein the lumen is sized to accept the filter element in its contracted state. Again, these are merely design choices that do not define a separate patentable invention from claim 6.

Since all of claims 6-15 define the same patentable invention as the proposed count, they should also be designated to correspond to the proposed count.

3. Claims 16-20 Are The Same Invention As The Proposed Count

Independent claim 16 is directed to the same patentable invention as the proposed count. None of claims 17-20, which depend from claim 1, adds any limitation that defines an invention separately patentable from claim 16, as discussed below.

As in the case of claim 6, claim 16 differs from the proposed count by identifying that the stop of the guide wire is formed by a greater thickness in the guidewire at the distal end. There is nothing nonobvious about forming the distal stop by having an increased thickness at the distal end of the guidewire. Claim 16 also differs from the proposed count in that claim 16 defines the filter element as a “sac” coupled to the capture ring. Again, there is nothing nonobvious about the filter being a sac, which is well known in the art. Claim 16 further differs from the proposed count by specifying that the capture ring of the filter element has an aperture greater than the narrow diameter of the guidewire (to facilitate translation over the guidewire), and less than the thicker diameter of the distal end of the guidewire (the stop). There is nothing nonobvious about the stop limiting translation of the capture ring by the greater thickness of the guidewire at its distal end. As discussed above, a thicker distal end of the guide wire is one of many means to create a stop. Claim 16 also differs from the proposed count in that the filter element is disposed for translation along the guidewire (as in the proposed count) by the guide wire extending through the aperture of the capture ring. This limitation adds nothing nonobvious over the apparatus of the proposed count. Claim 16 further differs from the proposed count in that after deployment in the vessel, rotation or distal translation of the guidewire does not displace the filter element. Again, as in claim 6, if the filter is attached to the capture ring and both are free to translate along the guidewire (as specified in the proposed count), there is nothing nonobvious about the necessary result that movement of the guidewire does not displace the expanded filter element. Finally, claim 16 differs from the proposed count in that claim 16 specifies that retraction of the guidewire in a proximal direction causes the distal region to abut against the capture ring. This limitation merely defines a necessary result from the recitations in the proposed count that the distal region has a stop with a diameter larger than the aperture of the capture ring.

Claim 17 adds the limitation to claim 16 that the filter element further comprises a plurality of self-expanding struts coupling the expandable sac to the capture ring. A filter element having a filter supported on a plurality of self-expanding struts is old in the art. See, for example, Patent No. 5,910,154 to Tsugita *et al.* (attached as Exhibit D),

Figures 6A and 6B, described at column 12, lines 11-15 and 33-37. Therefore, claim 17 does not define an invention separately patentable over the apparatus of claim 16.

Claim 18 adds the limitation to claim 17 that an elastomeric cone is affixed to a distal portion of the filter sac. The use of elastomeric materials on the distal ends of devices for use in the vasculature is old in the art. See, for example, Patent No. 5,466,234 to Loeb *et al.* (attached as Exhibit E), Figure 1, described at column 3, lines 66-67. Thus, use of an elastomeric cone on the distal portion of the filter sac is not a separately patentable invention over the apparatus of claim 17.

Claim 19 adds the limitation to claim 16 that the filter element further comprises a cylindrical sleeve coupled between the plurality of struts and the expandable base. This is also conventional in the art and would have been a nonobvious change to the apparatus of claims 16.

Claim 20 adds the limitation to claim 16 that the filter element further comprises a distal ring coupled to the expandable sac, the distal ring having a bore with a diameter greater than the second diameter. This additional limitation is also conventional in the art and in any event does not define a separately patentable invention over claim 16.

Therefore, claims 16-20 should also be designated to correspond to the proposed count since they are directed to the same patentable invention.

4. Claims 21-26 Are The Same Patentable Invention As The Count

Independent claim 21 is directed to the same patentable invention as the proposed count. None of claims 22-26, which depend from claim 21, adds any limitation that defines an invention separately patentable from claim 21, as discussed below.

Claim 21 differs from the proposed count in that claim 21 is directed to a method for using the apparatus of the proposed count. Since this is the only use for the apparatus of the proposed count, and the method is conventional in the art, claim 21 is nonobvious over the proposed count. Specifically, claim 21 recites providing the guidewire and filter element recited in the proposed count, inserting them transluminally into a vessel, deploying the filter element to engage a wall of the vessel to filter emboli, and advancing a treatment device along the guidewire to treat a portion of the vessel proximal to the filter element. All of these steps are conventional in the art. Claim 21 also differs from the proposed count by stating that rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. As discussed above, if the filter is attached to the capture ring and both are free to translate along the guidewire (as specified in

the proposed count), there is nothing nonobvious about the necessary result that movement of the guidewire does not displace the expanded filter element.

Claim 22 adds the limitation to claim 21 that, after use of the treatment device is completed, pulling the guidewire proximally so that the stop engages the capture ring and causes the filter element to return to the contracted state. This is clearly an obvious step so as to utilize the structural advantages of the apparatus defined in claim 21.

Claim 23 adds the limitation to claim 21 that the method further comprises providing a delivery sheath and compressing the filter element to a contracted state to insert the filter element within the delivery sheaths. Again, these kinds of steps are conventional in the art for delivering filter elements and do not define a separately patentable invention over claim 21.

Claim 24 adds the limitation to claim 21 that the filter element comprises an expandable sac, and deploying the filter element comprises expanding the expandable sac so that a perimeter of the sac contacts the wall of the vessel. These aspects of the method are also well known in the art and do not define a separately patentable invention.

Claim 25 adds the limitation to claim 24 that the filter element further comprises a cylindrical sleeve and deploying the filter element comprises expanding the cylindrical sleeve against the wall of the vessel. These aspects of the method are also well known in the art and do not define a separately patentable invention.

Claim 26 adds the limitation to claim 21 that the method further comprises providing a catheter having a lumen and pulling the guidewire proximally to cause the filter element to become retracted within the lumen. These additional aspects of the method are conventional in the art and do not define an invention separately patentable over claim 21.

Therefore, claims 21-26 should also be designated to correspond to the proposed count since they are directed to the same patentable invention.

Applicants' conclusion that all claims of the '859 patent are directed to the same patentable invention as the proposed count (which is identical to claim 1 of the patent) is consistent with the fact that the examiner did not require restriction among any of the claims of the '859 patent.

For the above reasons, all of claims 1-26 of the '859 patent should be designated to correspond to the proposed count.

**C. Claims 51-58 Of The Captioned Application
Are Supported In Applicants' Specification**

CLAIM 51: Support for claim 51 is found at page 1, lines 11-15; page 18, lines 3-8; page 19, lines 1-4; and page 18, lines 24-27, quoted below, and Figure 17.

51. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:	<i>The present invention deals with an emboli capturing system. More specifically, the present invention deals with an emboli capturing system and method for capturing embolic material in a blood vessel during an atherectomy or thrombectomy procedure (p. 1, ll. 11-15).</i>
a guide wire having a distal region and a stop on the distal region;	<i>Guidewire 210 is formed of an elongated wire 212, preferably having a spring coil tip 214, and a protective device docking member 216 coupled to a distal portion of wire 212, as illustrated in FIG. 17. Docking member 216 is rigidly coupled to wire 212 . . . (p. 18, ll. 3-8).</i>
a capture ring disposed for translation on the guide wire, the stop limiting translation of the capture ring in a distal direction; and	<i>Thus, device 230 is mounted relative to the guidewire by inserting guidewire 210 through an opening in cone 232. Device 230 is advanced over guidewire 210 to align cone 232 with docking member 216 (p. 19, ll. 1-4).</i>
a filter sac connected to the capture ring.	<i>Protection device 230 includes a distal cone 232, a filter 152, a frame 154, and a collar 156. Cone 232 is coupled to a distal end of filter 152 (p. 18, ll. 24-27).</i>

In the context of the captioned application, the phrase “capturing emboli” refers to removing emboli by filtration using a filter placed within a blood vessel. See, for example, the discussion at page 3, line 27 to page 4, line 2, and the general discussion of filters at page 9, lines 15-26. Generally, the distal “stop” and “capture ring” of claim 1 of the '859 patent correspond to the distal “docking member” 216 and “distal cone” 232 of Figures 17-20 of the captioned application, respectively. The docking member 216 functions as a stop to limit translation of the distal cone 232 in a distal direction. The filter 152 is attached to the distal cone 232.

CLAIM 52: Support for claim 52 is found at page 18, lines 22-24 and page 19, lines 3-4, quoted below, and Figure 18.

<p>52. The apparatus of claim 51 wherein, when the filter sac is deployed in the vessel, rotation or distal translation of the guide wire relative to the capture ring does not displace the filter sac, but retraction of the guide wire in a proximal direction causes the stop to abut against the capture ring.</p>	<p>FIG. 18 illustrates an embodiment of a protection device 230 which <i>may be</i> selectively coupled to docking member 216 (p. 18, ll. 22-24). Device 230 is advanced over guidewire 210 to align cone 232 with docking member 216 (p. 19, ll. 3-4).</p>
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As noted above and shown in Figure 18, the distal cone 232 of the filter sac may or may not be coupled to the docking member 216. When it is not coupled, the distal cone and filter sac freely rotate and distally translate (or advance) on the guide wire 210 in both the collapsed and deployed state.

CLAIM 53: Support for claim 53 is found at page 1, lines 11-15; page 18, lines 3-8; page 18, lines 26-33; page 18, lines 22-24; and p. 19, ll. 3-4, quoted below, and Figure 17.

<p>53. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:</p>	<p><i>The present invention deals with an emboli capturing system. More specifically, the present invention deals with an emboli capturing system and method for capturing embolic material in a blood vessel during an atherectomy or thrombectomy procedure (p. 1, ll. 11-15).</i></p>
<p>a guide wire having a first portion having a first diameter and a distal region having a second diameter greater than the first diameter; and</p>	<p><i>Guidewire 210 is formed of an elongated wire 212, preferably having a spring coil tip 214, and a protective device docking member 216 coupled to a distal portion of wire 212, as illustrated in FIG. 17. Docking member 216 is rigidly coupled to wire 212 . . . (p. 18, ll. 3-8).</i></p>

<p>a filter element having a capture ring disposed for translation on the first portion, the capture ring having an aperture greater than the first diameter but smaller than the second diameter,</p>	<p>Cone 232 is coupled to a distal end of filter 152. Cone 232 is generally "V"-shaped and is formed of a rigid member having a <i>distal opening (not shown) sized for insertion of guidewire 210 therethrough</i>. Cone 232 includes a locking ring 242 extending about an outer perimeter of cone 232. Locking ring 242 <i>is sized for insertion into groove 222 of docking member 216</i> (p. 18, ll. 26-33).</p>
<p>wherein rotation or distal translation of the guide wire relative to the capture ring does not displace the filter element.</p>	<p>FIG. 18 illustrates an embodiment of a <i>protection device 230 which may be selectively coupled to docking member 216</i> (p. 18, ll. 22-24). Device 230 is advanced over guidewire 210 to align cone 232 with docking member 216 (p. 19, ll. 3-4).</p>

In the context of the captioned application, the phrase "capturing emboli" refers to removing emboli by filtration using a filter placed within a blood vessel. See, for example, the discussion at page 3, line 27 to page 4 line 2, and the general discussion of filters at page 9, lines 15-26. Generally, the distal "stop" and "capture ring" of claim 1 of the '859 patent correspond to the distal "docking member" 216 and "distal cone" 232 of Figures 17-20 of the captioned application, respectively. The docking member 216 functions as a stop to limit translation of the distal cone 232 in a distal direction. It is a part of a typical guidewire and constitutes a second diameter greater than the diameter of the rest of the guidewire. The filter 152 is attached to the distal cone 232. As noted above and shown in Figure 18, the distal cone 232 of the filter sac may or may not be coupled to the docking member 216. When it is not coupled, the distal cone and filter sac freely rotate and distally translate (or advance) on the guide wire 210 in both the collapsed and deployed state.

CLAIM 54: Support for claim 54 is found at page 15, lines 19-22; and page 16, lines 32-33, quoted below.

<p>54. The apparatus of claim 53 wherein the filter element comprises an expandable sac.</p>	<p>Filter 152 may be formed from a polymer sheet material similar to that described for previous embodiments and filter holes or openings 180 may be formed therein by laser techniques (p. 15, ll. 19-22). Once sheath 64 is withdrawn from device 150, frame 154 and filter 152 expands radially outwardly . . . (p. 16, ll. 32-33).</p>
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Expandable filters are also shown throughout the figures of the captioned application.

CLAIM 55: Support for claim 55 is found at page 18, lines 3-6 and 26-33, quoted below, and Figure 18.

<p>55. The apparatus of claim 53 wherein the guide wire further comprises a flange disposed on the distal region having a diameter larger than the diameter of the aperture in the capture ring.</p>	<p>Guidewire 210 is formed of an elongated wire 212, preferably having a spring coil tip 214, and a protective device docking member 216 coupled to a distal portion of wire 212 . . . (p. 18, ll. 3-6). See FIG. 18.</p> <p>Cone 232 is coupled to a distal end of filter 152. Cone 232 is generally "V"-shaped and is formed of a rigid member having a <i>distal opening (not shown) sized for insertion of guidewire 210 therethrough</i>. Cone 232 includes a locking ring 242 extending about an outer perimeter of cone 232. Locking ring 242 <i>is sized for insertion into groove 222 of docking member 216</i> (p. 18, ll. 26-33).</p>
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Generally, the distal "stop" and "capture ring" of the claims of the '859 patent correspond to the distal "docking member" 216 and "distal cone" 232 of Figures 17-20 of the captioned application, respectively. The docking member 216 functions as a stop to limit translation of the distal cone 232 in a distal direction.

CLAIM 56: Support for claim 56 is found at page 1, lines 11-15; page 3, line 29 to page 4, line 2; page 14, lines 11-13; page 18, lines 3-8 and 22-33; and page 19, lines 1-6, quoted below, and Figures 17 and 18.

56. A method of filtering emboli from blood flowing through a vessel, the method comprising:	<i>The present invention deals with an emboli capturing system. More specifically, the present invention deals with an emboli capturing system and method for capturing embolic material in a blood vessel during an atherectomy or thrombectomy procedure (p. 1, ll. 11-15).</i>
providing a guide wire having a distal region including a stop, and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	<i>Guidewire 210 is formed of an elongated wire 212, preferably having a spring coil tip 214, and a protective device docking member 216 coupled to a distal portion of wire 212, as illustrated in FIG. 17. Docking member 216 is rigidly coupled to wire 212 . . . (p. 18, ll. 3-8). Protection device 230 includes a distal cone 232, a filter 152, a frame 154, and a collar 156. Cone 232 is coupled to a distal end of filter 152. Cone 232 is generally "V"-shaped and is formed of a rigid member having a distal opening (not shown) sized for insertion of guidewire 210 therethrough. Cone 232 includes a locking ring 242 extending about an outer perimeter of cone 232. Locking ring 242 is sized for insertion into groove 222 of docking member 216 (p. 18, ll. 24-33).</i>
transluminally inserting the guide wire and filter element into a vessel;	<i>Thus, device 230 is mounted relative to the guidewire by inserting guidewire 210 through an opening in cone 232. Device 230 is advanced over guidewire 210 to align cone 232 with docking member 216 (p. 19, ll. 1-6).</i>
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	<i>The device includes a proximally-tapered collapsible frame for operably supporting the filter between a collapsed insertion profile and an expanded deployment profile. The tapered frame includes a mouth which is sized to extend to walls of a body cavity in the expanded deployed profile for collecting emboli floating in the body cavity (p. 3, l. 29 to p. 4, l. 2).</i>

<p>advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.</p>	<p>Thereafter, treatment devices (not shown) may be advanced along guidewire 32 for placement relative to a stenosis 62 for treatment (p. 14, ll. 11-13). FIG. 18 illustrates an embodiment of a <i>protection device 230 which may be selectively coupled to docking member 216</i> (p. 18, ll. 22-24). Device 230 is advanced over guidewire 210 to align cone 232 with docking member 216 (p. 19, ll. 3-4).</p>
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In the context of the captioned application, the phrase “capturing emboli” refers to removing emboli by filtration using a filter placed within a blood vessel. See, for example, the discussion at page 3, line 27 to page 4 line 2, and the general discussion of filters at page 9, lines 15-26. Generally, the distal “stop” and “capture ring” of the claims of the ’859 patent correspond to the distal “docking member” 216 and “distal cone” 232 of Figures 17-20 of the captioned application, respectively. The docking member 216 functions as a stop to limit translation of the distal cone 232 in a distal direction. The filter 152 is attached to the distal cone 232. As noted above and shown in Figure 18, the distal cone 232 of the filter sac may or may not be coupled to the docking member 216. When it is not coupled, the distal cone and filter sac freely rotate and distally translate (or advance) on the guide wire 210 in both the collapsed and deployed state.

CLAIM 57: Support for claim 57 is found at page 19, lines 7-11, quoted below.

<p>57. The method of claim 56 further comprising: providing a delivery sheath; and compressing the filter element to a contracted state to insert the filter element within the delivery sheath.</p>	<p>Device 230 is inserted in a <i>low-profile collapsed condition</i> via cooperation with <i>sheath 64</i>, and is deployed by withdrawing sheath 64 while maintaining the position of guidewire 210 after device 230 is positioned at a treatment site . . . (p. 19, ll. 7-11).</p>
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CLAIM 58: Support for claim 58 is found at page 15, lines 16-22; and at page 16, line 30 to page 17, line 8, quoted below, and Figure 14.

58. The method of claim 57 wherein the filter element comprises an expandable sac, and deploying the filter element comprises expanding the expandable sac so that a perimeter of the expandable sac contacts the wall of the vessel.	<p>Filter 152 is preferably a cone-shaped member having proximal and distal ends 158, 160. The distal end 160 is generally "V"-shaped. Filter 152 may be formed from a polymer sheet material similar to that described for previous embodiments and filter holes or openings 180 may be formed therein by laser techniques (p. 15, ll. 16-22).</p> <p>To deploy the device, the sheath 64 is withdrawn while the operator maintains the position of guidewire 32. Once sheath 64 is withdrawn from device 150, frame 154 and <i>filter 152 expands radially outwardly</i> under the force of the compression spring 176 to expand mouth 170 to conform to the vessel walls 60 as illustrated in FIG. 14. Ribs 172 are extended outwardly to support mouth 170 in a radially- expanded position. The spring 176 maintains device 150 in a <i>deployed position so that mouth 170 conforms to the opening of the vessel</i>. Debris is captured and device 150 does not migrate under the load of the debris collected in filter 152 (p. 16, l. 30 to p. 17, l. 8).</p>
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D. Applicants' Claims 51-58 Should Be Designated To Correspond To The Proposed Count

The following table presents the correspondence between claims 51-58 of the captioned application and identical claims of the '859 patent:

<u>'859 Patent</u>	<u>Captioned Application</u>
1	51
2	52
6	53
7	54
11	55
21	56
23	59
24	58

Applicants' claims 51 corresponds identically to claim 1 of the '859 patent, which is identical to the proposed count. Therefore, claim 51 should be designated to correspond to the proposed count.

Applicants' claims 52-58 correspond substantially to the proposed count. In the section above, entitled "Claims 1-26 Of The '859 Patent Should Be Designated To Correspond To The Proposed Count," Applicants presented reasons why claims 1, 2, 6, 7, 11, 21, 23 and 24 of the '859 patent are directed to the same patentable invention as the proposed count. Since Applicants' claims 51-58 are identical to those patent claims, Applicants' claims 51-58 should be designated to correspond to the proposed count for the same reasons.

**III. APPLICANTS ARE ENTITLED TO THE BENEFIT OF
THE MARCH 5, 1998 FILING DATE OF THEIR PARENT
APPLICATION FOR THE PROPOSED COUNT**

Since the captioned application is a continuation application of the '740 application, both applications are identical. The showing above of support in the captioned application applies here to establish support in the '740 application as well. Additionally, there was co-pendency between the two applications since the captioned application was filed November 27, 2000, one day before the '740 application issued as a patent.

Thus, Applicants are entitled to the benefit of the March 5, 1998 filing date of their '740 application because that application meets the Section 112, first paragraph, written description and enablement requirements of at least one species within the proposed count. *Squires v. Corbett*, 560 F.2d 424, 433, 194 USPQ 513, 519 (C.C.P.A. 1977); *Weil v. Fritz*, 572 F.2d 856, 865-66 n.16, 196 USPQ 600, 608 n.16 (C.C.P.A. 1978).

**IV. THE EARLIEST POSSIBLE EFFECTIVE DATE
FOR BATES *ET AL.* IS JULY 16, 1999**

The '859 patent has no claim to priority under 35 U.S.C. §§ 119 or 120. Therefore, the earliest possible effective filing date for Bates *et al.* is the date application Serial No. 09/354,897 was filed, July 16, 1999.

V. BECAUSE APPLICANTS' EFFECTIVE FILING DATE IS PRIOR TO THE EFFECTIVE DATE OF THE '859 PATENT, A DECLARATION UNDER 37 C.F.R. § 1.608(a) IS SUFFICIENT

Applicants have established above that their effective filing date for the subject matter of the proposed count is March 5, 1998 and the earliest possible effective filing date of the '859 patent is July 16, 1999. Since Applicants' date is prior to the earliest possible effective filing date of the '859 patent. Applicants need file only an affidavit (declaration) under 37 C.F.R. § 1.608(a) alleging that there is a basis upon which Applicants are entitled to judgment relative to the patentee of the '859 patent. An appropriate Declaration of Thomas E. Friebe Under 37 C.F.R. § 1.608(a) accompanies this Request.

VI. COMPLIANCE WITH 35 U.S.C. § 135(b)

The provision of 35 U.S.C. § 135(b)(1) is not an impediment to adding the new claims because they were added to this application within one year of the issuance of the '859 patent, which issued January 30, 2001. The provision of 35 U.S.C. § 135(b)(2) is not an impediment to adding the new claims because the '859 patent was not published under 35 U.S.C. § 122(b).


CONCLUSION

Applicants have demonstrated that they are entitled to declaration of an interference between the captioned application and Bates *et al.* Patent No. 6,179,859. The count should be Applicants' proposed count, which is identical to claim 1 of the '859 patent. Applicants' claims 51-58 should be designated as corresponding to the proposed count, and Applicants should be accorded the benefit of the filing date of application Serial No. 09/035,740, filed March 5, 1998. Bates *et al.* claims 1-26 should be designated as corresponding to the proposed count, and Bates should be accorded its filing date of July 16,

1999. Therefore, Applicants should be named senior party. Applicants have complied with 35 U.S.C. § 135(b).

Respectfully submitted,

Date January 29, 2002

 29,258

Thomas E. Friebe (Reg. No.)

PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090

Attachments:

- Exhibit A: List of pending claims 51-58
- Exhibit B: Bates *et al.*, Patent No. 6,179,859 B1 (the “859 patent”)
- Exhibit C: Broome *et al.*, Patent No. 6,152,946
- Exhibit D: Tsugita *et al.*, Patent No. 5,910,154
- Exhibit E: Loeb *et al.*, Patent No. 5,466,234